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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,244	12/22/2003	Isabelle Chacornac	FRAV2002/0041 US NP	6970

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EXAMINER	
SHEIKH, HUMERA N	

ART UNIT	PAPER NUMBER
1615	

NOTIFICATION DATE	DELIVERY MODE
07/16/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/743,244	CHACORNAC ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *16-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2/27/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Response to Restriction/Election and Applicant's Arguments/Remarks, filed 04/27/07 and the Information Disclosure Statement filed 02/27/04 is acknowledged.

Applicant's election with traverse of Group I (claims 1-15) in the reply filed on 04/27/07 is acknowledged. The traversal is on the ground(s) that "The search of all of claims 1-20 should not impose an undue burden on the Examiner" and that "Group II recites a method for the preparation of a composition having the same scope as that of Group I." Applicant also argues, "Both invention groups are in the same class of 424 for search purposes and differ only by a subclass". This is not found persuasive because, as noted in the Restriction requirement, the scope of the Group I invention is different from that of the Group II invention. Namely, the Group I composition claims require the use of a surfactant, whereas in the Group II process of making invention, no surfactant is required. Additionally, the Group I claims recite optional incorporation of a wax, whereas the Group II claims do not recite the use of wax (either required or optional). Thus, the scopes of the claimed inventions are not the same. Moreover, the Group I invention would require a different search than that of the Group II invention, and there is no expectation that the search would be coextensive in scope. Thus, Applicant's arguments were not found persuasive.

The requirement is still deemed proper and is therefore made FINAL.

Claims 16-20 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 04/27/07.

Claims 1-20 are pending in this action. Claims 16-20 have been withdrawn. Claims 1-15 are rejected.

Inventorship

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 3-10 recite the limitation "by weight of the total mixture of the composition" in each of claims 3-10. There is insufficient antecedent basis for this limitation in the claim.

Claim 3 is also indefinite because the claim is a broader claim than claim 1, from which it depends. Claim 3, which recites the limitation of "an ester of glycerol present between about *50% and about 85%* by weight..." is indefinite because the range of glycerol ester is outside the range claimed in claim 1, which is about 60% to about 80%. The "85%" of claim 3 falls outside of the maximum upper limit of "80%" of claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Venkatesh *et al.* (U.S. Patent No. 6,475,510).

The instant invention is drawn to a composition intended for the oral administration of active ingredients with unacceptable taste, which comprises from about 15 to about 30% of active ingredient mixed with from about 60% to about 80% of an ester of glycerol or of a fatty acid, to which a wax is optionally added, and to which a surfactant is added, and wherein the composition is prepared by a spray-cooling process which can produce a particle size of less than about 350 μm.

Venkatesh *et al.* ('510) teach a fast-dispersible tablet for oral administration containing an active ingredient, a waxy material and a sweetener and/or a taste-masking agent to reduce bitter tasting ingredients (see col. 3, line 14 – col. 4, line 5).

The intragranular mixture requires blending of components, which include one or more medicaments, a component which is a waxy material and a taste-masking agent such as the lipoproteins and phospholipids derived from soy lecithin (col. 4, line 10 – col. 5, line 30).

Suitable waxy materials include mono-, di- or tri- aliphatic esters of glycerol, preferably glycerol palmitostearate (Precirol®) (col. 5, lines 31-39).

Suitable taste-masking agents in the intragranular formulation include the lipoproteins and phospholipids derived from soy lecithin (col. 5, lines 40-44).

Pharmaceutically active ingredients are disclosed at column 6, lines 9-35. The medicament can be comprised in 1-60 parts by weight (col. 7, lines 44-45).

The waxy material is present at a level of from about 1% to about 30%. While this range is lower than Applicant's claimed range of about 60% to about 80%, the Examiner points out

that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). It is the position of the Examiner that suitable or effective amounts of glycerol and/or fatty acid can be determined by one of ordinary skill in the art through the use of routine or manipulative experimentation to obtain optimal results, as these are indeed variable parameters attainable within the art.

The waxy material, taste-masking agents and sweetener agents for use in the intragranular component may also be optionally used in the extragranular admixture (col. 6, lines 5-8).

Additional excipients, such as flavoring agents, disintegrants and lubricants such as stearic acid can also be added to the formulation (col. 6, line 43 – col. 7, line 53); (col. 8, lines 1-10).

The Examples at columns 9-14 demonstrate various tablet formulations comprising active ingredient, waxy materials such as Precirol®, phospholipids and excipients (see for instance, Examples 2-4).

While Venkatesh *et al.* do not explicitly teach a particle size of less than about 350 μm, it is noted that the claim language "which can produce a particle size of less than about 350 μm" imparts future-intended use language and thus, does not afford patentable weight to the claims. Moreover, no unexpected results accrue from the instantly claimed particle size. Effective

particle sizes can be determined by one of ordinary skill in the art through the routine optimization process.

Venkatesh *et al.* explicitly teach an orally administered tablet formulation comprising a blended intragranular admixture of pharmaceutically active ingredient, waxy materials, sweetening agent and/or taste-masking agent, and surfactant. The formulations are used to mask the bitter taste of active ingredients. The reference teaches and recognizes tablet formulations comprising essentially the same components as that being claimed by Applicant. Thus, given the teachings of Venkatesh *et al.* delineated above, the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday during regular business hours. (Telework on Wednesdays).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh

Primary Examiner

Art Unit 1615

July 09, 2007

HUMERA N SHEIKH
PRIMARY EXAMINER

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